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Attention: Docket No. OPPTS-50639
Document Control Office (7407)
Office Of Pollution Prevention And Toxics (OPPT)
U.S. Environmental Protection Agency
East Tower Room (G-099)
Waterside Mall
401 M Street, S. W.
Washington, D. C. 20460

Re: **Perfluorooctyl Sulfonates; Proposed Significant New Use Rule, 65 Fed. Reg. 62319 (Oct. 18, 2000)**

Dear Sir and Madam:

3M submits these comments on the significant new use rule proposed by the U.S. Environmental Protection Agency ("EPA" or "the Agency) for perfluorooctyl sulfonates. See Perfluorooctyl Sulfonates; Proposed Significant New Use Rule, 65 Federal Register 62319 (Oct. 18, 2000) [hereinafter "PFOS SNUR Proposal" or "the Proposal"]. 3M currently manufactures and distributes numerous products based on perfluorooctanyl chemistry. The great bulk of these products are derived from perfluorooctanesulfonyl fluoride (POSF) and may degrade under some conditions to perfluorooctanesulfonic acid (PFOS). POSF and its derivative substances, including PFOS, largely comprise the chemicals subject to the PFOS SNUR Proposal, and the Proposal refers to these chemicals collectively as "perfluorooctyl sulfonates."

On May 16, 2000, 3M announced its decision to phase-out the manufacture of all products based on perfluorooctanyl chemistry. In this announcement, 3M indicated that its worldwide production of these materials would be discontinued substantially by the end of 2000 and that 3M would work with its customers to implement an orderly phase-out. 3M's phase-out decision was based on its commitment to responsible environmental management and sound business

principles. Notably, the extensive data base for these compounds -- which is publicly available through the OPPTS "For Your Information" Docket No. AR-226 -- indicates no association of adverse effects with the PFOS levels measured either in the environment or in the general population.

In these comments, 3M first provides further information on its phase-out plan as background and context for the PFOS SNUR Proposal. We then address certain aspects of EPA's characterization of the health and environmental data base on PFOS in the preamble to and accompanying docket for the Proposal. Finally, 3M requests technical corrections to the PFOS SNUR Proposal.

I. 3M'S VOLUNTARY PHASE-OUT PLAN

For the past two years, 3M has been involved in an ongoing dialogue with EPA and others regarding PFOS and other POSF-derivative compounds. This dialogue stems from a series of TSCA Section 8(e) submissions by 3M beginning in May of 1998, which reported the measurement of PFOS and related compounds in general population human serum and in wildlife at low parts per billion (ppb) levels.

As part of this dialogue, 3M has provided EPA with "white papers" summarizing available information on the chemistry, use and distribution, and health and environmental effects profile of PFOS and related chemicals. 3M also has updated EPA regularly as new data become available from 3M's ongoing research program.

In May of this year, 3M decided to discontinue manufacture of POSF and derivative substances. 3M made this decision on a voluntary basis because of its commitment to responsible environmental management and sound business principles. 3M concluded that, in light of the persistence of PFOS and other POSF-derivative compounds and the detection of these compounds at extremely low levels in the blood of the general population and wildlife, other business opportunities were more deserving of the company's energies and attention. As 3M has emphasized in the context of its phase-out decision, the extensive data base for these compounds indicates no association of adverse effects with the PFOS levels measured either in the environment or in the general population.

On July 7, 2000, 3M supplied EPA with the details of our voluntary plan for accomplishing the phase-out. This plan, which 3M has been implementing in recent months, provides for a substantial reduction in overall worldwide production of POSF-derivative compounds after December 31, 2000, with limited production continuing through the end of 2002, at which time, 3M manufacture would cease altogether on a worldwide basis.

In undertaking to develop its voluntary phase-out plan, 3M understood that POSF-derivative compounds are used in a wide range of applications touching

numerous segments of the economy. Accordingly, a major goal of 3M's plan was to minimize marketplace disruption and to provide for an orderly transition away from these compounds. For this purpose, 3M devised a careful evaluation process to select "extended phase-out" applications for which continued production would be justified in the 2001-2002 period. Using this process, 3M identified several products used by customers or other 3M businesses which were deemed suitable for extended phase-out in 2001-2002.

Although the PFOS SNUR Proposal is an outgrowth of 3M's phase-out plan for POSF-derivative compounds, it is important to recognize that 3M decided to phase out perfluorooctanyl chemistry on a voluntary basis. Indeed, 3M did not ask EPA to issue a SNUR; nor do we believe a SNUR is needed to assure successful implementation of 3M's phase-out decision. 3M remains committed to implementation of its phase-out plan and is on target to achieve a substantial scale-down in production by the end of 2000.

II. HEALTH AND ENVIRONMENTAL EFFECTS DATA AND OTHER INFORMATION UNDERLYING THE PFOS SNUR PROPOSAL

Beginning in 1998, 3M presented -- on its own initiative -- a series of overview papers on PFOS and related compounds to EPA:

⇒ January 21, 1999 paper entitled "Perfluorooctane Sulfonate: Current Summary of Human Sera, Health and Toxicology Data;"

⇒ February 5, 1999 paper on "The Science of Organic Fluorochemistry;"

⇒ May 26, 1999 paper, "Fluorochemical Use, Distribution and Release Overview;" and

⇒ March 1, 2000 paper entitled "Sulfonated Perfluorochemicals in the Environment: Sources, Dispersion, Fate and Effects."

More recently, 3M prepared robust summaries of all data on PFOS available as of July 20, 2000 and summarized this data in a draft Initial Assessment Report on PFOS and its salts. The report -- which 3M has submitted to the OPPTS "For Your Information" Docket No. AR-226 -- was jointly authored by 3M's in-house scientists and several recognized outside experts in the health and environmental fields. 3M's independent Science Advisory Panel also commented on this draft. 3M shared this draft Report first with EPA in September 2000, and then with representatives from the Organization For Economic And Community Development (OECD) at a working session in October and a meeting for the OECD Taskforce for Existing Chemicals in November 2000. We plan to revise the draft Report in response to comments from OECD and as new data becomes available from ongoing or planned studies.

While the summary findings presented in the Federal Register notice supporting the SNUR are generally consistent with the weight of the evidence as presented in the draft Report, we do wish to offer several specific comments on statements in the preamble to the Proposal as well as the EPA Hazard Assessment Memorandum in the docket accompanying the Proposal:

Introductory Statement

⇒ The acronyms used by EPA in the Federal Register notice are inconsistent with the terminology 3M has employed in all of its papers, document submissions, studies, published papers and the Draft Initial Assessment Report. For ease of communication, EPA may wish to adopt the same terminology that appears in all of the documentation. This terminology was set out in the Perfluorochemical Glossary at Table 1 in the March 2000 environmental paper, and used throughout the document submissions.

⇒ More specifically, the use of the acronym PFOS for perfluorooctyl sulfonates, collectively referring to the perfluorooctane sulfonate ion, perfluorooctanesulfonic acid, and the associated salts is consistent with existing documentation. 3M has not, however, included perfluorooctane sulfonyl fluoride (which we call POSF) within this term.

⇒ We also suggest EPA not refer to perfluorooctane sulfonic acid as PFOSA, as 3M has used that abbreviation (or FOSA) to refer to perfluorooctanesulfonamide. We have used PFOSH to refer to the acid.

⇒ Finally, we have referred to perfluorooctane sulfonyl fluoride as POSF rather than PFOSF.

Environmental Fate

⇒ We are not aware of any experimental or empirical data to support EPA's model prediction that PFOS would partition almost equally between water and soil (69 Fed. Reg. at 62325).

⇒ The water solubility values in the same paragraph of the proposed SNUR preamble are taken from 3M's submission in March 2000. Improved, GLP values have been presented in studies subsequently submitted to EPA (e.g., 519 mg/L in pure water rather than 570 mg/L) and should be referenced in lieu of these earlier numbers. Additional data will be forthcoming.

Health Effects Discussion

⇒ In the discussion of the two-generation study (65 Fed. Reg. at 62326), EPA refers to NOAEL and LOAEL levels for the second generation offspring (F2 pups) which are based on reductions in pup body weight as compared to controls on lactation days 7 and 14. Those reductions were subsequently reversed; the reduction in body weight observed in the 0.4 mg/kg/day dose-group F2 pups on lactation days 7 and 14 was not statistically different from the controls at the $p < 0.05$ level on lactation day 21. Thus, to be accurate, the sentence should refer to these NOAEL and LOAEL levels as being for "transient" reductions in pup body weight.

⇒ At the end of the discussion of the two-generation study, EPA correctly notes there were some observations of "reversible delays in reflex and physical development." These delays were highly correlated with body weight, and as noted were transient. The study reported that these observations were not toxicologically important except for certain responses at the 1.6 mg/kg/day dose. Moreover, as EPA's Hazard Assessment Memorandum notes, "There were no statistically significant differences reported for any of the following parameters: values for learning, short-term retention, long-term retention or response inhibition as evaluated by performance in a passive avoidance or watermaze performance paradigm. . . ." In light of these findings, EPA's suggestion that the reversible delays in certain developmental parameters "raises concerns" about potential developmental neurotoxicity overstates the significance of the reported findings. We therefore request EPA delete the suggestion of concern, and add mention that there were no effects on these other measures of neurobehavioral development.

⇒ In the paragraph on developmental effects, the discussion omits mention of either fetal or maternal NOELs or LOELs (in contrast to the discussion of the reproductive study). Given the occurrence of maternal toxicity accompanying the observation of developmental effects, the paragraph could be misleading without the fetal and maternal NOEL and LOEL information. We request that EPA add this information to any such discussion in the final rule.

⇒ The report of ocular lens abnormalities in an early developmental study has not been replicated in multiple subsequent studies, including one of identical dose and design. Mention of this finding -- even with the acknowledgement it has not been replicated -- in the very brief summary of health effects in the SNUR overplays its significance. 3M devoted substantial effort to addressing this issue, and outside experts concluded the asserted defects in the early study were in fact an artifact of tissue sectioning. 3M has submitted detailed information to EPA on this issue. We believe the issue has been conclusively addressed, and

should not be "controversial". Rather, as the EPA Hazard Assessment Memorandum indicates, EPA simply has the matter under review. The need for further review by EPA, however, should not disproportionately elevate the refuted findings. Given the quality and large amount of subsequent data, the reference to lens abnormalities in the SNUR is inappropriate in our view and should be deleted from any final rule.

⇒ EPA may wish to clarify the paragraph on human serum levels by noting the mean level for workers as well as the maximum.

⇒ The mention (again on page 62326) of serum levels in "a very small sample of children" being "even higher" than adults is inappropriate. These data consisted of only ten pediatric serum samples. As the EPA Hazard Assessment Memorandum (at page 23) notes: "few inferences can be made about the results of these data." The memorandum also notes that a 3M study of 600 pediatric serum samples is ongoing. EPA should delete the sentence regarding children's serum levels from the preamble, since the data are insufficient for drawing any conclusions. Additional data will be forthcoming.

We also offer two additional comments with regard to the EPA Hazard Assessment Memorandum:

⇒ As noted in the Draft Initial Assessment Report, 3M is presently conducting additional work to characterize the purity of samples used in testing and analysis over the last several years, and we expect to refine the analytical values for serum and liver PFOS concentrations in the animal studies. Thus, the values given on page 4 of the EPA Hazard Assessment Memorandum will be subject to further refinement.

⇒ Table 1 in the EPA Hazard Assessment Memorandum mistates the range of serum values found in the 3M Sagamihara plant management and Tokyo head office personnel because it fails to account for the non-detect readings noted in the text of the report of that study.

III. TECHNICAL CORRECTIONS

3M requests slight modifications to both Tables 2 and 3 in the PFOS SNUR Proposal. Specifically, the following CAS numbers should be removed from Table 2 and placed on Table 3: 68156-01-4, 117806-54-9, 55120-77-9, 423-82-5. 3M inadvertently omitted these CAS numbers from Attachment 4 to our phase-out plan provided to EPA on July 7, 2000. These CAS numbers correspond to homologues of chemicals already included in Table 3 of the Proposed SNUR, and just as with the other chemicals on Table 3, the product applications associated with these CAS numbers qualify under 3M's phase-out plan for extended use treatment.

Additionally, 3M believes that section IV (A) *Defining PFOS* does not accurately reflect the background and context for -- and the data base underlying -- the PFOS SNUR. As the circumstances detailed in Section I above indicate, the PFOS SNUR Proposal is an outgrowth of 3M's phase-out plan, and thus, the Proposal is intended to regulate fluorinated C-8 sulfonate-containing substances. Moreover, as the discussion in Section II above reflects, the data base and information underlying the PFOS SNUR Proposal all relate to C-8 sulfonate-containing substances.

Accordingly, the PFOS definition should be reworded to reference species containing primarily C-8 material and to exclude those chemical species that do not contain C-8 species. In this context, 3M would note that the use of an alkyl range definition for PFOS in this section is inappropriate because it implies that substances consisting of, for example, four or five perfluorinated carbons are also subject to the SNUR, even when they are not present in a substance comprising a range of carbon lengths that include C-8. Alkyl ranges containing C-8 should be covered by the SNUR, so as to regulate the C8 content of such substances. The PFOS SNUR (including the "Defining PFOS" section and Tables 2 and 3), however, should not include any C-4 or C-5 species as separate and distinct chemical substances. Accordingly, 3M also requests the removal of CAS 148240-79-3 and CAS 148240-81-7 (found in Table 2) from the PFOS SNUR. Neither of these CAS numbers, nor the associated PMN numbers, were referenced in the 3M phase-out plan, and these CAS numbers do not correspond to homologues that include C-8.

* * *

3M appreciates this opportunity to comment on the PFOS SNUR Proposal. I will be retiring from 3M effective January 4, 2001. You may feel free to contact me until then, or after that, please contact my successor, Michael Santoro, at (651) 733-6374 with any questions.

Very truly yours,

William A. Weppner

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